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## FDA's Role in Foreign Drug Manufacturing

**Host:** Captain Catherine Chew

**Pharmacist:** Lieutenant Commander Lindsay Wagner

**CAPT Chew:** Americans expect and deserve safe, effective, and high-quality medications. That is why FDA works with both domestic and foreign manufacturers to help ensure that products distributed within the United States meet U.S. requirements and standards for product safety and quality.

Hi, I'm Captain Catherine Chew, and this is Drug Info Rounds, brought to you by the pharmacists in FDA's Division of Drug Information.

The FDA is often asked how we help ensure that products distributed within the United States are safe to take. My colleague, LCDR Lindsay Wagner, will explain several ways FDA oversees drug manufacturing.

**LCDR Wagner:** FDA provides an important oversight function to assess compliance with applicable regulations, including Current Good Manufacturing Practices. FDA inspects drug manufacturers as part of the process of reviewing new and generic drug product applications and performs routine surveillance inspections of manufacturing facilities throughout a product's lifetime on the market.

Another tool the agency employs to check quality is testing of finished drugs and sometimes key ingredients, which may be sampled from retail stores, distribution warehouses, and manufacturing sites. The results of this testing are available at FDA's Drug Quality Sampling and Testing website.

In addition to carrying out routine surveillance inspections, FDA will inspect a facility on a "for-cause" basis when a specific product quality or safety problem comes to the FDA's attention, such as a known or suspected contamination or other public health threat. During the post-market surveillance phase of a product's lifecycle, the agency may receive complaints from consumers, health care professionals, and others reporting on a drug product defect. This information helps FDA identify the need for additional surveillance activity that can lead to regulatory actions, like recalls, warning letters, injunctions, seizures, import refusals, and in some instances, criminal cases against manufacturers that engage in violative practices.

**CAPT Chew:** Will you go into more detail about how FDA prioritizes inspections?

**LCDR Wagner:** To help ensure that drugs manufactured both within and outside of the U.S. are safe and of high quality, FDA uses a risk-based inspection schedule for both domestic and foreign drug facilities. FDA determines which drug establishments to inspect, regardless of geographic location, based on known safety risks, including:

- the establishment's compliance history;
- product recalls linked to the establishment;
- inherent risks of the drug product manufactured at the establishment;
- the establishment's inspectional history, including both the FDA and other regulators' inspections; and
- other factors that the FDA considers necessary in determining how to allocate inspection resources.

In this global pharmaceutical environment, FDA is aligning its inspectional and surveillance approach based on risk to public health. This refined approach sharpens our focus on high-risk issues that are critical to quality and aligns our resources to provide the most impact to consumer safety.

FDA can only evaluate the quality of drugs in legal commerce. FDA does not oversee the manufacturing of drugs that are being distributed illegally in the United States, including drugs that are imported or illegally enter into the U.S. Medicine purchased on the internet from foreign sources, from storefront businesses that offer to buy foreign medicine for you, or during trips outside the United States, may not be safe or effective. These medicines may present health risks, and FDA cannot ensure the safety of medicine from these sources.

**CAPT Chew:** The FDA is transforming from a domestically-focused agency to a proactive, global public health agency in order to carry out our mission more effectively in a world where trade, and product safety and quality, have no borders. If you have questions about FDA's role in foreign drug manufacturing, call or email FDA's Division of Drug Information.